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PTO/SB/08A (10-96)
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Substitute for form 1449A/PTO

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet

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of

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Application Number	10/706,243
Filing Date	November 12, 2003
First Named Inventor	Robert S. Feldstein
Group Art Unit	1616
Examiner Name	George, Konata M.
Attorney Docket Number	PDT 103 CON (3)

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	US Patent Document		Name of Patentee or Applicant of Cited Document	Date of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code ² (if known)			
		4,153,689		Hirai	05-08-1979	
		4,196,196		Tiholiz	04-01-1980	
		4,211,769		Okada	07-08-1980	
		4,294,829		Suzuki	10-13-1981	
		4,659,696		Hirai	04-21-19	
		4,946,828		Markussen	08-07-1990	
		5,006,343		Benson	04-09-1991	
		5,042,975		Chien	08-27-1991	
		5,204,108		Illum	04-20-1993	
		5,354,562		Platz	10-11-1994	
		5,364,838		Rubsamen	11-15-1994	
		5,482,927		Maniar	01-09-1996	
		5,484,606		Dhabar, et al.	01-16-1996	

FOREIGN PATENT DOCUMENTS

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		Office ³	Number ⁴	Kind Code ⁵ (if known)				
		EP	0/069/715		Draco AB	01-12-1983		
		EP	0/122/036		Teijin Ltd	10-17-1984		
		EP	0/237/507		Draco AB	09-16-1987		
		EP	0 220 958 A2		Eli Lilly and Company	05-06-1987		
		EP	0/360/340		Akzo	03-28-1990		
		EP	0/364/235		Toyo Jozo Kabushiki	04-18-1990		
		EP	0/606/486		Teijin Ltd.	12-23-1993		

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				First Named Inventor	Robert S. Feldstein
				Group Art Unit	1616
				Examiner Name	George, Konata M.
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		Number	Kind Code ² (if known)			
	5,503,852			Steiner et al.	04-02-1996	
	5,514,646			Chance, et al.	05-07-1996	
	5,547,929			Anderson Jr. et al.	08-20-1996	
	5,562,909			Allcock, et al.	10-08-1996	
	5,693,338			Milstein	12-02-1997	
	5,763,396			Weiner, et al.	06-09-1998	
	5,785,989			Stanley, et al.	07-28-1998	
	5,807,315			Van Antwerp, et al.	09-1998	
	5,849,322			Ebert, et al.	12-15-1998	
	5,877,174			Ono, et al.	03-02-1999	
	5,888,477			Gonda et al.	03-30-1999	
	5,912,011			Makino, et al.	06-15-1999	
	5,929,027			Takama, et al.	07-27-1999	

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	EP	0655237			Hoechst AG	03-26-1996		
	EP	0748213			Inhale Therapeutic Sys	12-18-1996		
	EP	1/114/644			Genetech, Inc.	07-11-2001		
	EP	96911738			Nektar Therapeutics	06-16-2004		
	PCT	WO 90/13285			Enzytech, Inc	11-15-1990		

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First Named Inventor	Robert S. Feldstein
Group Art Unit	1616
Examiner Name	George, Konata M.

Sheet 3 of 10 Attorney Docket Number PDT 103 CON (3)

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		5,976,569		Milstein	11-02-1999	
		5,985,309		Edwards, et al.	11-16-1999	
		6,051,256		Platz, et al.	04-18-2000	
		6,071,497		Steiner, et al.	06-06-2000	
		6,099,517		Daughterty	09-08-2000	
		6,153,613		Ono, et al.	11-28-2000	
		6,254,854		Edwards, et al.	07-03-2001	
		6,294,204		Rossling, et al.	09-25-2001	
		6,331,318		Milstein	12-18-2001	
		6,395,744		Adams, et al.	05-28-2005	
		6,395,774		Milstein	05-28-2002	
		6,423,344		Platz, et al.	07-23-2002	
		6,428,771		Steiner, et al.	08-06-2002	

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		PCT	WO 91/16882		Lipsome Technology	11-14-1991		
		PCT	WO 92/04069		Aktiebolaget astra	03-1992		
		PCT	WO 93/17728		Aktiebolaget Astra	09-1993		
		PCT	WO 93/02712		Danbiosyst UK Limited	02-18-1993		
		PCT	WO 94/000291		Fisons Plc	01-06-1994		
		PCT	WO 95/00127		Astra Atkiebolag	00-1995		
		PCT	WO 95/11666		Coordinated Drug	05-04-1995		

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				Filing Date	November 12, 2003
				First Named Inventor	Robert S. Feldstein
				Group Art Unit	1616
				Examiner Name	George, Konata M.
Sheet	4	of	10	Attorney Docket Number	PDT 103 CON (3)

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		Number	Kind Code ² (if known)			
		6,432,383		Modi	08-13-2002	
		6,436,443		Edwards, et al.	08-20-2002	
		6,440,463		Feldstein, et al.	08-27-2002	
		6,444,226		Steiner, et al.	09-03-2002	
		6,447,753		Edwards, et al.	09-10-2002	
		6,503,480		Edwards, et al.	01-07-2003	
		6,518,239		Kuo, et al.	02-11-2003	
		6,592,904		Platz, et al.	07-15-2003	
		6,635,283		Edwards, et al.	10-21-2003	
		6,652,885		Steiner, et al.	11-25-2003	
		6,652,885		Steiner et al	11-25-2003	
		6,676,931		Dugger, III	01-13-2004	
		6,685,967		Patton	02-03-2003	
		6,737,045		Patton	05-18-2004	

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		Office ³	Number ⁴	Kind Code ⁵ (if known)			
		PCT	WO 95/31979		R.P Scherer International	11-30-1995	
		PCT	WO 95/34294		Hamilton, Brook, Smith, & Reynolds P.C. and Yissum	12-21-1995	
		PCT	WO 96/36314		Pharmaceutical Discovery Corporation	11-21-1996	
		PCT	WO 97/49386		Peptide Delivery Systems	12-31-1997	

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				Filing Date	November 12, 2003
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				Group Art Unit	1616
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		Number	Kind Code ² (if known)			
		6,949,258		Zhang	09-24-2005	
		7,030,084		Ekwuribe, et al.	04-18-2006	
		RE35,862		Steiner, et al.	07-28-1998	
		RE37,053		Hanes, et al.	02-13-2001	
		2003/0064097		Patel, et al.	04-03-2003	
		2003/0068378		Chen, et al.	04-10-2003	
		2003/0194420		Holl, et al.	10-16-2003	
		2004/0151774		Pauletti, et al.	08-05-2004	
		2004/0247628		Lintz, et al.	12-09-2004	
		2004/157928		Kim Jae-Hwan, et al.	08-12-2004	
		2005/0080000		Thurow Horst, et al.	04-14-2005	
		2005/0153874		Cheatham	07-14-2005	

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		PCT	WO 99/52506		Aventis Research & Technologies	10-21-1999	
		PCT	WO 01/00654		Steiner	01-2001	
		PCT	WO 01/07107		PharmaceuticalDiscovery Corporation	02-01-2001	
		PCT	WO 03/057170		Emisphere Technologies	07-17-2003	

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		2004/0077528		Steiner	04-22-2004	
		2005/0214251		Steiner	03-11-2005	
		2007/0086952		Steiner	9-29-2006	
		6,582,728		Platz	06-24-2003	
		2004/0182387		Steiner	09-23-2004	
		2004/0096403		Steiner	05-20-2004	

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		PCT	WO 03/086345		Atrix Laboratories, Inc.	10-23-2003	
		PCT	WO 03/094951		Novo Nordisk As	11-20-2003	
		PCT	WO 04/056314		Nastech Pharmaceutical Company Inc	07-08-2004	
		PCT	WO 05/089722		Biodel , Inc	09-29-2005	
		PCT	04/075919		Medtronic Minimed, Inc	09-10-2004	
		PCT	02/11676		DMI Biosciences, Inc.	02-14-2002	

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OTHER ART -- NON PATENT LITERATURE DOCUMENTS			
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		BAUER, et al., "Assessment of beta-adrenergic receptor blockade after isamoltane, a 5-HT1-receptor active compound, in healthy volunteers," <i>Clin. Pharmacol Ther</i> 53:76-83 (1993).	
		BRANGE, et al., "Insulin Structure and stability", <i>Pharm Biotechnol.</i> , 5:315-50 (1993).	
		CERASI, et al., "Decreased sensitivity of the pancreatic beta cells to glucose in prediabetic and diabetic subjects. A glucose dose-response study," <i>Diabetes</i> 21(4): 224-34 (1972).	
		CEFALU, et al, "Inhaled Human Insulin Treatment in Patients with type 2 diabetes mellitus," <i>Ann. Int. Med.</i> , 134: 203-7 (2001).	
		CHEATHAM and PFEUTZNER, "Desirable dynamics & performance of inhaled insulin compared to subcutaneous insulin given at mealtime in type 2 diabetes: A report from the technosphere/insulin study group" <i>Diabetes Technology & Therapeutics</i> 6:234-235 (2004).	
		COSTELLO, et al., "Zinc inhibition of mitochondrial aconitase and its importance in citrate metabolism in prostate epithelial cells", <i>Journ. Biol. Chem.</i> , 272(46):28875-28881 (1997).	
		DIETER KÖHLER, "Aerosols for Systemic Treatment", <i>Lung (Suppl)</i> , 677-684 (1990).	
		DUNN, "Zinc-ligand interactions modulate assembly and stability of the insulin hexamer", <i>Biometals</i> , 18(4):295-303 (2005).	
		EDELMAN, "Type II Diabetes Mellitus," <i>Advances in Internal Medicine</i> , 43:449-500 (1998).(Abstract)	
		ENGELGAU, et al., "Screening for type 2 diabetes," <i>Diabetes Care</i> 15(3):1-31 (2000).	

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OTHER ART -- NON PATENT LITERATURE DOCUMENTS		
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		FESTA, et al., "LDL particle size in relation to insulin, proinsulin, and insulin sensitivity" <i>Diabetes Care</i> 22(10):1688-1693 (1999).
		GARBER, "Premixed insulin analogues for the treatment of diabetes mellitus", <i>Drugs</i> , 66(1):31-49 (2006).
		HAFFNER, et al., "Proinsulin and insulin concentrations I relation to carotid wall thickness" <i>Stroke</i> 29:1498-1503 (1998).
		HAGEDORN, et al., "Protamine insulin", <i>JAMA</i> , 106:177-180 (1936).
		HANLEY et al., "Cross-sectional and prospective associations between proinsulin and cardiovascular disease risk factors in a population experiencing rapid cultural transition" <i>Diabetes Care</i> 24(7):1240-1247 (2001).
		HEUBNER, et al. <i>Klinische Wochenschrift</i> 16,2342 (1924)
		HEYDER, "Alveolar deposition of inhaled particles in humans," <i>Am. Ind. Hyg. Assoc. J.</i> 43(11): 864-866 (1982).
		JOHNSON, et al., "Turbuhaler®: a new device for dry powder terbutaline inhalation," <i>Allergy</i> 43(5):392-395 (1988)
		KOHLER, et al., "Pulmonary Administration . . . , Abstract 298, <i>Diabetes</i> 33 (Suppl.):75A (1984).
		KOHLER, "Aerosols for Systemic Treatment", <i>Lung Suppl.</i> 677-683 (1990)
		KONTNY, et al. "Issues Surrounding MDI Formulation Development with Non-CFC Propellants," <i>J. Aerosol Med.</i> 4(3), 181-187 (1991).

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)		Application Number	10/706,243
Sheet	9	of	10
Filing Date	November 12, 2003		
First Named Inventor	Robert S. Feldstein		
Group Art Unit	1616		
Examiner Name	George, Konata M.		
Attorney Docket Number	PDT 103 CON (3)		

OTHER ART – NON PATENT LITERATURE DOCUMENTS			
Examiner's Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T ²
		LEAHY, "Beta-cell dysfunction in type II diabetes mellitus," <i>Curr. Opin. Endocrinol. Diabetes</i> 2(4): 300-306 (1995).	
		LEE, et al., "Development of an Aerosol Dosage Form Containing Insulin," <i>J. Pharm. Sci.</i> 65(4), 567-572 (1976).	
		LIAN, et al., "A self-complementary, self-assembling microsphere system: application for intravenous delivery of the antiepileptic and neuroprotectant compound felbamate," <i>J Pharm Sci</i> 89:867-875 (2000).	
		NAGAI, et al., "Powder Dosage Form of Insulin for Nasal Administration," <i>J. Control Rel.</i> , 1:15-22 (1984).	
		PFEIFFER, "Insulin secretion in diabetes mellitus," <i>Am. J. Med.</i> 70(3): 579-88 (1981).	
		PFUTZNER, et al., "Influence of small dose i.v., s.c. and pulmonary insulin treatment on prandial glucose control in patients with type 2 diabetes" <i>37th Annual Meeting of the EASD, Glasgow, 9-13 September 2001</i> 812 (2001) (abstract).	
		POLONSKY, et al., "Abnormal patterns of insulin secretion in non-insulin-dependent diabetes mellitus," <i>N. England J. Med.</i> 318(19): 1231-39 (1988).	
		PRABHU, et al. "A study of factors controlling dissolution kinetic of zinc complexed protein suspensions in various ionic species", <i>Int. J. Pharm.</i> , 217(1-2):71-8 (2001).	
		RASKIN, et al., "Continuous subcutaneous insulin infusion and multiple daily injection therapy are equally effective in type 2 diabetes" <i>Diabetes Care</i> 26:2598-2603 (2003).	
		ROSENSTOCK, et al., "Reduced hypoglycemia risk with insulin glargine: a meta-analysis comparing insulin glargine with human NPH insulin in type 2 diabetes", <i>Diabetes Care</i> , 28(4):950-5 (2005).	
		SCHLUTER, et al., "Pulmonary Administration of Human Insulin in Volunteers and Type I Diabetics", <i>Diabetes</i> , 33 (Suppl.): 298 (1984)	

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Sheet	10	of	10	Attorney Docket Number	PDT 103 CON (3)
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		SCHNEIDER, et al., "Stimulation by proinsulin of expression of plasminogen activator inhibitor type-I in endothelial cells" <i>Diabetes</i> 41(7):890-895 (1992).	
		WARREN, et al., "Postprandial versus preprandial dosing of biphasic insulin aspart in elderly type 2 diabetes patients" <i>Diabetes Research and Clinical Practice</i> 66:23-29 (2004).	
		WATERHOUSE, et al. "Comparative assessment of a new breath-actuated inhaler in patients with reversible airways obstruction." <i>Respiration</i> 59:155-158 (1992).	
		ZETHELIUS, et al., "Proinsulin is an Independent Predictor of Coronary Heart Disease" <i>Circulation</i> 105:2153-2158 (2002).	
		BERGE, et al. "Pharmaceutical Salts," <i>J. Pharmaceutical Sciences</i> 66(1):1-19 (1997).	
		HEINEMANN, et al. "Current Status of the development of inhaled insulin" <i>Br. J. Diabetes Vasc Dis</i> 4:295-301 (2004).	
		STEINER, et al. "Technosphere™/ Insulin- proof of concept study with new insulin formulation for pulmonary delivery" <i>Exp. Clin. Endocrinol. Diabetes</i> 110:17-21 (2002).	
		KOHLER, et al. "Non-radioactive approach for measuring lung permeability: inhalation of insulin," <i>Atemw Lungebrkrkh</i> 13:230-232 (1987). (Original in German and English Translation attached).	
		RAZ, et al. "Pharmacodynamic and pharmacokinetics of dose ranging effects of oralin versus s.c. regular insulin in Type 1 diabetic patients," <i>Fourth Annual Diabetes Technology Meeting</i> , Philadelphia, PA, 2004.	

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